

EPA Issues Test Rule on 17 HPV Substances; Withdraws Testing Proposal for 20 Others

On March 16, 2006, EPA promulgated a final rule under Section 4 of the Toxic Substances Control Act (TSCA), imposing new testing requirements on 17 chemical substances that the Agency determined are produced in high volumes. 71 Fed. Reg. 13707, to be codified at 40 C.F.R. § 799.5985(j). The 17 substances are:

CAS No.	Chemical Name
74-95-3	Methane, dibromo-
75-36-5	Acetyl chloride
78-11-5	1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester)
84-65-1	9,10-Anthracenedione
108-19-0	Imidodicarbonic diamide
110-44-1	2,4-Hexadienoic acid, (2E,4E)-
112-52-7	Dodecane, 1-chloro
118-82-1	Phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)]-
149-44-0	Methanesulfinic acid, hydroxy-, monosodium salt
409-02-9	Heptenone, methyl-
594-42-3	Methanesulfonyl chloride, trichloro-
624-83-9	Methane, isocyanato-
1324-76-1	Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]-
2941-64-2	Carbonochloridothioic acid, S-ethyl ester
8005-02-5	C.I. Solvent Black 7
65996-78-3	Light oil (coal), coke-oven
68611-64-3	Urea, reaction products with formaldehyde

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The rule will become effective on April 17, 2006. Current manufacturers, including companies that import these chemicals, must submit letters of intent to test or applications for exemption from the testing requirement so that they are received by EPA no later than May 15, 2006. Companies that commence manufacture or import of any of the chemicals after May 15, 2006 but prior to the close of the testing cost reimbursement period, must submit letters of intent to test or applications for exemption prior to commencing manufacture or importation.

The tests required under this rule are the Screening Information Data Set (SIDS) adopted by the Organization for Economic Cooperation and Development. SIDS testing evaluates six testing endpoints: (1) acute toxicity; (2) repeat dose toxicity; (3) developmental and reproductive toxicity; (4) genetic toxicity (gene mutations and chromosomal aberrations); (5) ecotoxicity; and (6) environmental fate. Specific test requirements for each chemical are set forth in the rule.

The 17 chemicals that are subject to this rule are “orphan” chemicals from the Agency’s voluntary High Production Volume (HPV) testing initiative, launched in 1998 in an attempt to gather basic toxicity test data on chemicals that EPA determined were being manufactured and/or imported in amounts equal to or greater than 1 million pounds annually. Since the HPV program’s inception, chemical manufacturers and importers have committed to test over 2,200 chemicals. Some chemicals, however, remain “un-sponsored” and EPA’s rule is an attempt to force mandatory testing for some of these substances.

EPA’s initial proposed test rule (65 Fed. Reg. 81,686 (Dec. 26, 2000)) would have extended these mandatory testing requirements to an additional 20 chemicals, but in the interim since the proposed rule, EPA determined that such requirements were unnecessary. In that interim, companies have come forward and committed to sponsor testing on 11 of the chemicals under the HPV program, and two more are being sponsored as part of a parallel HPV testing initiative by the International Council of Chemical Associations. For another seven of the chemicals, EPA has determined that they no longer are produced and/or imported in amounts equal to or greater than 1 million pounds annually.

When final, this test rule will require submission of data, and as such renders each of the 17 chemicals subject to the export notification requirements of TSCA Section 12(b), as detailed at 40 C.F.R. § 707. Anyone intending to export any of these chemicals to a foreign country must submit notification to EPA prior to the first export to each country.

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